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| 10/564,874 | 01/17/2006 | Hiroyuki Shimoji | SAEG124.005APC | 3870 |
| 29995 7590 05/29/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | | |
| EXAMINER ORKIN, ALEXANDER J | | | | |
| ART UNIT 3773 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/564,874

Applicant(s)

SHIMOJI ET AL.

Examiner

ALEXANDER ORKIN

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to after-final amendment filed 5/15/2009. The finality of the previous office action filed on 02/17/2009 has been dropped, however this office action is final due to the amendments filed 12/18/2008.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 4, 6, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 6,551,350 to Thornton et al. in view of U.S. Patent 2,259,025 to Cosgro.

As to claims 1, 6, Igaki discloses a tubular suture reinforcement material made from stacking two sheet-like material and sewing together both ends using two stitches. Igaki invention is described by combining two sheets of materials by sewing two opposite sides to create the tubular structure. The ends of the threads are extended to a suitable length. Additionally, Igaki discloses the ends of the threads can be tied into a knot that is capable of forming a loop (Fig 1, col. 3, ll. 30-43). The thread end is passed through an anterior loop continuous to the thread end. The anterior loop can be the loop of the knot. Igaki does not specifically say the knot will prevent unraveling however that is what knots are used for. Cosgro teaches that a knot at the end of a chain stitch will prevent the stitch from unraveling (figure 5, col. 3 ll. 3-22). Additionally, Igaki lacks the two chain stitch used in creating the tubular structure. Instead they disclose a normal stitch. However it is commonly known in the art to use a chain stitch such. Thornton teaches the chain stitch concept using only one thread. The stitch has each loop going through the prior loop just like how the chain stitch is defined in this application (Fig. 7a-c, col. 14, ll. 41-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

modify the stitch of Igaki with the chain stitch of Thornton and use the knot of Igaki in or order to better prevent unraveling.

As to claims 3, with the device of Igaki, Cosgro and Thornton, Igaki further discloses the material of the tubular suture reinforcement material being made up from a biodegradable and bioabsorbable knitted, woven, unwoven fabric etc (col. 3, ll. 1-12).

As to claims 4, Igaki, Cosgro and Thornton, Igaki discloses that these materials can be stacked on top of each other with one of them being stretchable in order to make the tubular shape (col. 3, ll. 1-12).

As to claims 10, Igaki, Cosgro and Thornton, Igaki disclose the method for manufacturing a tubular suture reinforcement material for an automatic suturing device by first stacking two sheet like materials, then sewing together both ends the sides of the sheet-like material to form the tubular structure. Second, extend the thread ends and passing the thread end through the previous loop (col. 3 1-20). The loop is the loop of a knot (col. 3 ll. 34). The stitch is the chain stitch from Thornton.

As to claims 11, Igaki, Cosgro and Thornton, Igaki further discloses the automatic suture device comprising a cartridge with staples and a frame that has a staple receiving slot wherein a tubular suture reinforcement material for an automatic suturing device is fitted to the cartridge and/or frame (Fig. 5).

As to claims 12, Igaki, Cosgro and Thornton, Igaki discloses the method of removing an affected part of a tissue, which could be a lesion from a patient by

first sandwiching the tissue in the unwoven fabrics. The tissue is then separated by a cutter. Finally the end of the suture is pulled to separate the section remaining in vivo and the section removed. This leaves part of the material inside the body, while removing some of the material along with the affected part (figure 5-7, col. 3 ll 33-53).

As to claims 13 and 14, Igaki, Cosgro and Thornton, Igaki discloses using this method in either a soft tissue or in a pulmonary tissue (col. 4, ll. 53-59)

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 6,551,350 to Thornton et al. in view of U.S. Patent 2,259,025 to Cosgro. and further in view of U.S. U.S. Patent No. 6,063,097 to Oi et al.

As to claim 2, Igaki Thornton, and Cosgro teach the tubular suture reinforcement material. However, they lack the tapered end.

Oi teaches the tubular reinforcement material having the tip part sewed in a tapering fashion (Fig. 7). It would have been obvious to one of ordinary skill of the art to modify the tip part of the material to make be sewn in a tapered manner in order to prevent turn up of the supporting element

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,766,188 to Igaki in view of U.S. Patent 6,551,350 to Thornton et al. in view of U.S. Patent 2,259,025 to Cosgro. and further in view of U.S. Patent No. 6,273,897 to Dalessandro et al.

As to claim 5, Igaki Thornton, and Cosgro teach the tubular suture reinforcement material. However, they lack the projections on the sewing portion of the reinforcement material.

Dalessandro teaches projections on a buttress or a suture reinforcement material. These projections can make it easier to slide the buttress onto the instrument (Fig 12, 13a, 13b, col. 3, ll. 50-2). This same function of using the projections to make it easier to slide a device on the instrument can be used with Igaki Thornton, and Cosgro in loading the suture reinforcement material onto the instrument. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify tubular structure of Igaki with the projection of Dalessandro in order to make it easier to load the tubular suture reinforcement material onto the automatic suturing device.

Response to Arguments

8. Applicant's arguments, see pgs 2-6, filed 5/15/2009, with respect to the rejection(s) of claim(s) 1-6, 10-14 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Patent 2,259,025 to Cosgro.

The applicant correctly argues that Thornton does not have the means of prevention of unraveling, Thornton only has the type of stitch, a chain stitch. However, in Igaki, a knot is used that will prevent unraveling. This means is better taught in Cosgro of preventing unraveling by looping the thread end through an anterior loop.

Additionally the anterior loop can be the knot that Igaki discloses that will inherently prevent unraveling. The knot loop will be continuous of the thread end based on the fact there is one thread so it has to be continuous. The final combination of Igaki, which discloses the tubular structure along with the knot for prevention of unraveling, Thornton, which discloses a chain stitch, and Cosgro, which further teaches means to stop unraveling, reads on the claims as disclosed.

9. Applicant's request for reconsideration of the finality of the rejection of the last Office action filed on 02/17/2009 is persuasive and, therefore, the finality of that action is withdrawn.

Conclusion

10. Applicant's amendment filed on 12/18/2009 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER ORKIN whose telephone number is (571)270-7412. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. O./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773